

## **REMARKS**

The above amendments and these remarks are responsive to the non-final Office action dated December 8, 2006, and are being filed under 37 C.F.R. § 1.111. Claims 28–30, 33–41, 83, 84, and 88–90 are pending in the application. Claim 83 is the only independent claim. In the Office action, the Examiner rejected each of the pending claims under 35 U.S.C. § 102 or § 103 as being anticipated and/or obvious. In particular, the Examiner rejected:

- Claims 28, 30, 37–41, 83, 89, and 90 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,410,255 to Pollok et al. (“Pollok”);
- Claim 29 under 35 U.S.C. § 103(a) as being unpatentable over Pollok;
- Claim 33 under 35 U.S.C. § 103(a) as being unpatentable over Pollok in view of U.S. Patent No. 5,674,698 to Zarling et al.;
- Claim 84 under 35 U.S.C. § 103(a) as being unpatentable over Pollok in view of U.S. Patent No. 6,524,790 to Kopf-Sill et al.; and
- Claims 34–36 and 83 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,586,193 to Yguerabide et al. (“Yguerabide”) in view of Pollok.

Applicants traverse the rejections, contending that none of the pending claims is anticipated or obvious. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants want to patent now, applicants have (1) canceled claim 90, without prejudice, and (2) amended claims 29, 33–35, 83, and 88. However, applicants reserve the right to pursue the canceled claim and/or the amended claims, in original or previously presented form, at a later time. Furthermore, applicants have presented arguments showing that the pending claims are patentable over the cited references. Accordingly, applicants respectfully request reconsideration of the application in view of the amendments above and the

remarks below, and prompt issuance of a Notice of Allowability covering all of the pending claims.

**I. Claim Rejections – 35 U.S.C. §§ 102 and 103**

The Examiner rejected all of the pending claims under 35 U.S.C. § 102(e) and/or § 103(a) as being anticipated by or obvious over Pollok alone or in combination with another reference. Applicants traverse the rejections, contending that none of the cited references, taken alone or in combination, teaches or suggests every element of any of the pending claims. Nevertheless, for the reasons set forth above, applicants have amended independent claim 83, which is the only independent claim pending in the application, as noted above.

Claim 83 has been amended by the present communication as follows:

83. (Currently Amended) A kit for detecting enzyme activity in a sample, the kit comprising:  
an enzyme;  
a luminophore bound to a substrate for the enzyme; and  
a particulate mass label distinct from the enzyme and capable of specifically binding to ~~the substrate~~ or a product of the substrate produced by action of the enzyme on the substrate, but not **capable of specifically binding to the substrate** ~~[[both]]~~, the particulate mass label including a bead;  
wherein a luminescence property of the luminophore is sensitive to binding of the mass label to the ~~substrate~~ or product.

Claim 83 was rejected in the Office action over (A) Pollok alone, and (B) Yguerabide and Pollok. Claim 83 is patentable over each of the cited references because the cited references do not teach or suggest every element of claim 83, for the reasons set forth below.

A. Rejections over Pollok

Claim 83 was rejected as being anticipated by Pollok. However, Pollok does not teach or suggest every element of claim 83. For example, Pollok does not teach or suggest a particulate mass label “capable of specifically binding to a product of the substrate, but not capable of specifically binding to the substrate.”

Pollok relates to optical probes and assays. Figure 1 of Pollok, which is reproduced here to facilitate review, provides schematic representations of various embodiments of Pollok's probes.

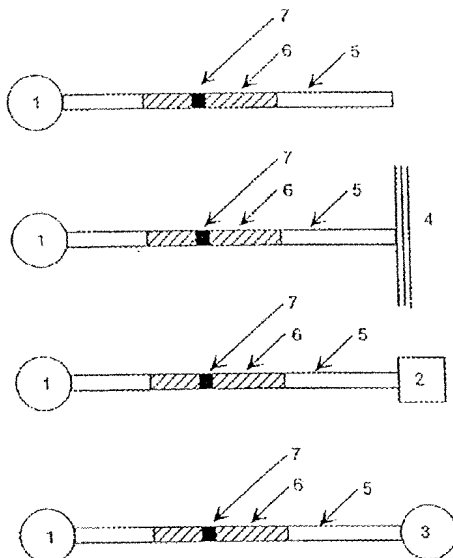


FIG. 1

Each probe is stated to include a polypeptide 5 with a post-translational modification recognition site 6, such as for phosphorylation by a kinase or dephosphorylation by a phosphatase, and a protease site 7 for protease-based cleavage of the polypeptide. The polypeptide is attached to a probe moiety 1 that provides an optical probe for optical detection of changes to the structure of the polypeptide. In some cases, the polypeptide also may be attached to a solid surface 4, such as a bead.

Pollok also discloses assays for enzymes of interest that measure enzyme activity indirectly via protease cleavage. More particularly, protease site 7 is positioned within post-translational modification recognition site 6 such that post-translational modification of site 6 by an enzyme of interest changes the efficiency with which the polypeptide is cleaved by a protease. For example, the assays are disclosed to measure kinase activity indirectly by an effect of phosphorylation on protease cleavage of the polypeptide.

In the Office action, the Examiner specifically cited column 25, lines 4-6, 9, and 30-36, of Pollok to reject claim 83. This section of Pollok involves fluorescence polarization assays that measure changes in the fluorescence anisotropy of an optical probe produced by protease cleavage. The optical probe is disclosed to have the structure presented above in Figure 1, for example, a polypeptide attached to both a bead and to a fluorescence moiety. Accordingly, Pollok discloses a bead attached to both a substrate and a product of the substrate, since the bead is bound to the substrate polypeptide before protease cleavage and remains bound to a fragment (a product) of the substrate polypeptide after protease cleavage. In contrast, claim 83 recites a particulate mass label “capable of specifically binding to a product of the substrate produced by action of the enzyme on the substrate, but not capable of specifically binding to the substrate.”

Therefore, for at least these reasons, independent claim 83 should be patentable over Pollok. Claims 28–30, 33–41, 84, 88, and 89, which depend from claim 83, also should be patentable over Pollok for at least the same reasons as claim 83.

*B. Rejections over Yguerabide and Pollok*

Claim 83 also was rejected as being unpatentable over a combination of Yguerabide and Pollok. However, neither Yguerabide nor Pollok, taken alone or in combination, teaches or suggests every element of claim 83. For example, neither reference teaches or suggests a particulate mass label “capable of specifically binding to a product of the substrate, but not capable of specifically binding to the substrate.”

Yguerabide relates to analyte assays with particulate labels. In the Office action, the Examiner asserted that Yguerabide discloses all elements of claim 83 except a luminescent probe bound to a substrate for an enzyme, citing column 86, line 66, to column 87, line 8, of Yguerabide. The cited section of Yguerabide relates to cleavage assays in which a light scattering particle is attached to a substrate for a cleavage enzyme or ribozyme. However, Yguerabide discloses a cleavage assay analogous to that of Pollok, in which a light scattering particle is attached both to a substrate and to a product of the substrate produced by cleavage of the substrate. In contrast, claim 83 recites a particulate mass label “capable of specifically binding to a product of the substrate produced by action of the enzyme on the substrate, but not capable of specifically binding to the substrate.” Accordingly, neither Yguerabide nor Pollok (see subsection A above) teaches or suggests the particulate mass label of claim 83 that is binds the product but not the substrate.

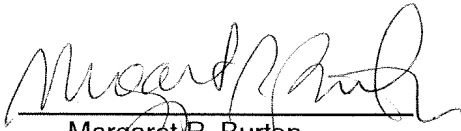
Therefore, for at least these reasons, claim 83 should be patentable over Yguerabide and Pollok. Claims 34–36, which depend from claim 83 and also were rejected over Yguerabide and Pollok, also should be patentable over Yguerabide and Pollok for at least the same reasons as claim 83.

## **II. Conclusion**

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

### **CERTIFICATE OF ELECTRONIC FILING**

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